

Non-Vertebrate Testing Methods (NAMs)

LANGUAGE:

SAC Report pg.83

The Committee notes that the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Public Law 114–182) directed the Agency to report to Congress on efforts to advance non-animal testing and goals for future alternative test methods and strategies implementation. Once finalized, the Agency is directed to brief the Committee on the findings of this report, as well as the Agency’s experience with submitters developing information by means of an alternative test method or strategy before conducting new vertebrate animal testing, consistent with Section 4(h)(3)(A) of the act.

The Committee also notes that new approach methodologies [NAMs], including in vitro tests, in chemical assays and in silico models, represent key advances in science to support hazard and risk assessments of pesticides and chemicals. The Committee encourages the Agency to continue supporting and performing research on the development and evaluation of NAMs through the Chemical Safety for Sustainability National Research Program.

HAC Report pg.85

In an effort to reduce animal testing across EPA, the Committee directs the Agency to provide a briefing, within 90 days of enactment of this Act, detailing the timeline for reducing and replacing experiments on vertebrate animals, as well as any actions EPA has taken to date that change goals set in 2019–2020.

Additionally, pursuant to Section 4(h)(2)© of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Committee directs EPA to publish information regarding New Approach Methods, including submissions that are currently being evaluated and those that have been rejected, and, as EPA finalizes its report on regulatory flexibility regarding animal testing within the agency and for accommodating the use of NAMs, EPA should incorporate specific goals that reflect the current regulatory landscape and outline the necessary steps to reduce animal testing and to assess progress.

VIEWS:

- EPA supports this directive.
- EPA delivered the Report to Congress on efforts to advance non-animal testing and goals for future alternative test methods and strategies implementation in December 2021.
- Substantial progress has been made in recent years. In 2020, *EPA New Approach Methods Work Plan: Reducing Use of Animals in Chemical Testing* was issued followed by an updated workplan in December 2021. In addition, EPA has released new documents for waiving dermal acute pesticide studies, adopting the use of *in vitro* studies for skin sensitization and skin absorption, a quantitative approach for mixture testing, and reducing the use of birds and fish in pesticide testing.
- EPA is working closely with stakeholders, academia, and other governmental agencies to advance the science.
- During the 2022 *EPA Conference on State of the Sciences on Development and Use of NAMs for Chemical Safety Testing*, the Agency released its FY19 – FY21 animal use metrics for ORD and OPP. The release of the animal use metrics was a deliverable in the *EPA New Approach Methods Work Plan*.
- EPA’s Office of Pesticide Programs has made substantial progress in the last few years to reduce the use of laboratory animals and begin implementation of NAMs. Progress is provided on the program’s webpage <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/strategic-vision-adopting-new-approach-methodologies> and in the “Science Review/Assessment Improvements”

sections of the recent PRIA reports to Congress <https://www.epa.gov/pria-fees/annual-reports-pria-implementation>.

- EPA's Office of Pesticide Programs and Office of Pollution Prevention and Toxics have ongoing collaborative efforts related to human health and ecotoxicology with EPA's Office of Research and Development, industry, NGOs and other governments to advance the development and implementation of NAMs.
- EPA provides the information required by TSCA section 4(h)(2)(c) at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/strategic-plan-reduce-use-vertebrate-animals-chemical>.
- In 2022, EPA announced a new collaborative effort under the Toxic Substances Control Act (TSCA) with the Office of Research and Development and other federal entities to modernize the process and bring innovative science to the review of new chemicals before they can enter the marketplace. This research will focus on in vitro and computational approaches for human health and ecological evaluations. <https://www.epa.gov/newsreleases/epa-announces-collaborative-research-program-support-new-chemical-reviews>
- Additional information on EPA's efforts on NAMs is available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>.